Discussions on safety and efficiency of medicine "Rigvir"

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Monday, the 2nd of October, the Ministry of Health held a meeting where experts* discussed an issue of safety and efficiency of medicine "Rigvir".

During the meeting the State Agency of Medicines (SAM) pointed out that in 2004 SAM and independent experts concluded that the information gathered from clinical trials with the medicine was sufficient to register it for local treatment of cutaneous and subcutaneous metastases of melanoma, prevention of recurrences and metastases after radical surgery.

Stability studies at -20◦C were submitted and they allowed registration of the medicine, yet they had to be continued to make absolutely sure that the medicine remains stable during its storage period. Therefore registration of medicine "Rigvir" was temporarily suspended until additional stability studies had been submitted. Registration of the medicine was resumed on 18 May 2005.

During re-registering of a medicine one evaluates whether post-registration experience and use of medicine do not show any new risks due to which safety information of the medicine should be changed. After evaluating all the submitted documents, including safety reports subject to updating, benefit and risk balance of medicine "Rigvir" was determined as favourable in 2009.

According to regulation applicable to the pharmacy industry, healthcare professionals and pharmacists must report to SAM about observed side effects of any medicines, by providing in-depth and accurate information to ensure that a report can be scientifically analysed within the framework of pharmacovigilance system.

During discussions the oncologists from Riga Eastern Clinical Hospital pointed out that a broader discussion would be welcome among oncologists regarding application of medicine "Rigvir" in treating melanoma, because so far specialists have varied opinions. Also before the Association of Oncologists invited the Ministry of Health and State Agency of Medicines to review an issue on registration of medicine "Rigvir" no wider discussions had taken place thus allowing for improper interpretation of such proposal.

Representatives of medicine "Rigvir" emphasized that currently an intensive work at construction of a new production plant and science centre is taking place as well as necessary steps are taken for central registration of the medicine in the European Medicines Agency. Studies of melanoma treatment are also continued.

However, in the opinion of the State Agency of Medicines, the owner of registration certificate must improve conformity to drug safety supervision requirements, acquisition of therapeutic efficiency data and modernize the production plant of raw materials.

The meeting was concluded with a view that professional discussion should take place among oncologists regarding updating of melanoma treatment guidelines as well as the owner of registration certificate of "Rigvir" should continue studies in area of efficiency of the medicine.

** The meeting was attended by representatives of the Ministry of Health, the State Agency of Medicines, National Health Service, Riga Eastern Clinical University Hospital, Riga Stradins University Pharmacology Department as well as representatives of the manufacturer of medicine "Rigvir".*